UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/829,316 | 04/21/2004 | Joel R. Studin | SDF 04-14 | 5671 |

7590 05/13/2009

Stuart D. Frenkel
Suite 330
3975 University Drive
Fairfax, VA 22030

| EXAMINER | |
|---|---|
| SHEIKH, HUMERA N | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 05/13/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/829,316
Filing Date: April 21, 2004
Appellant(s): STUDIN, JOEL R.

Phillip R. Kiefer
Reg. No. 55,326
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 09 February 2009 appealing from the Office action mailed 19 August 2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Examiner notes for co-pending Application No. 10/829,315 a Notice of Appeal was filed on April 7, 2009.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| 5,968,519 | YOUSSEFYEH et al. | 10-1999 |
| 5,446,070 | MANTELLE | 8-1995 |
| 5,552,162 | LEE | 9-1996 |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

- (A) Claims 1-16 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh *et al.* (U.S. Patent No. 5,968,519) in view of Lee (U.S. Patent No. 5,552,162).

- (B) Claims 1-16 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Patent No. 5,446,070) in view of Lee (U.S. Patent No. 5,552,162).

* * * * *

- **(A) Claims 1-16 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh *et al.* (U.S. Patent No. 5,968,519) in view of Lee (U.S. Patent No. 5,552,162).**

**Youssefyeh *et al.* ('519)** teach a method for the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, urticaria, psoriasis, erythema), gingivitis and acute injury with a composition of finely divided powder of safflower seed or its extract contained in a pharmaceutically acceptable carrier (see Abstract); (column 1, lines 10-18). Youssefyeh teach that the method of treatment for the relief of inflammation and/or pain associated with inflammatory dermatoses such as eczema, urticaria, psoriasis and the like comprises topically administering a therapeutically effective amount of a finely divided powder of safflower seed or its extract sufficient to induce alleviation of signs, symptoms or causes of inflammation or pain in a pharmaceutically acceptable carrier (col. 11, line 49 – col. 12, line 58); (col. 13, line 53 – col. 14, line 7); (col. 22, line 64 – col. 24, line 13). Youssefyeh teach that for topical administration, the compositions may contain certain pharmaceutical and therapeutical agents either singularly or in combination of which suitable pharmaceutical/therapeutical agents disclosed include anti-inflammatory corticosteroids, such as progesterone, hydrocortisone, prednisone, triamcinolone and dexamethasone. Additional agents disclosed include anti-inflammatory analgesics, local anesthetics, antibacterial agents and antiseptic agents. It is also taught that the topical compositions can be in the forms of ointments, creams, lotions, solutions, dressings and patches and slow-release preparations and film-forming preparations (col. 14, lines 19-40); (col. 15, lines 29-60).

Topical formulations can be prepared by combining the finely divided safflower seed or its extract with conventional pharmaceutical carriers or diluents used in topical dry, liquid and cream formulations. Ointments and creams may be formulated with an aqueous or oil base with the addition of suitable thickening or gelling agents (col. 15, lines 29-60). Ointments, pastes, creams and gels may contain excipients such as cellulose derivatives and silicones (col. 15, lines 43-46).

A preferred form of topical delivery is film-forming materials loaded with finely divided powder of safflower seed or its extract. Suitable film-forming materials taught include cellulosic derivatives, such as methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose and other synthetic polymers (col. 15, line 61 – col. 17, line 19); and claim 12. Upon application, the formulation is deposited on the desired area and allowed to form a film, which by the presence of water in the skin environment, will allow slow delivery of the active agent onto the area being treated (col. 17, lines 20-23).

Applicants claim, "hardening the carrier into a tangible membrane" in claim 1. The instant claims differ from the prior art in that Youssefyeh do not specifically teach a "membrane" as instantly claimed. However, they nonetheless teach that the topical formulation is deposited onto the desired area and allowed to *form a film*, which will allow for slow release of active agent onto the treatment area. Thus, the "film" taught by Youssefyeh is functionally equivalent to the "membrane" claimed by Applicant.

While the prior art does not explicitly teach treatment of "healed wounds", the prior art nonetheless explicitly teaches methods for treating inflammatory dermal conditions, both acute and chronic and teaches that suitable topical applications include film-forming preparations (see

col. 13, line 53 – col. 14, line 40). The method comprises topical administration of safflower oil in combination with a corticosteroid and a pharmaceutically acceptable carrier, whereby upon application, the formulation is deposited on the skin to form a film for the release of active agent onto the treatment area. The methods of treatment and conditions to be treated as taught by Youssefyeh would include application upon healed wounds so as to reduce scarring and/or improve the appearance thereof.

Youssefyeh do not teach vitamin E, collagenase and treating a hypertrophic scar.

**Lee ('162)** teach a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound healing disorder that comprises stimulating collagenase activity in the scar. The method comprises covering the scar with a hydrogel or thermally insulated material that elevates the surface temperature of the scar and that can contain a therapeutically effective amount of medicament (see Abstract); (column 1, lines 41-54); (col. 6, lines 17-49); (col. 11, lines 19-34).

Lee teaches that the collagenase is provided in the composition in order for the effective breakdown and degradation of collagen (col. 7, lines 44-62). Vitamins such as vitamin E are included in the composition (col. 11, lines 35-52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, such as hypertrophic scars such as taught by Lee within the methods of Youssefyeh. One would do so with a reasonable expectation of success because Lee explicitly teaches methods for improving the size and appearance of scars, including hypertrophic scars, which comprises applying a thermal material or hydrogel

containing suitable ingredients such as vitamin E and collagenase, used for the degradation of collagen. The expected result would an enhanced method for treating dermatological disorders and conditions.

* * * * *

**(10) Response to Argument (A):**

*Note*: Independent Claims 1 and 30 have been argued separately and are addressed below.

Claim 1:

Appellant argues, "Youssefyeh does not teach or suggest a method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars. Youssefyeh teaches a method for the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, urticaria, psoriasis, erythema), gingivitis and acute injury. Treatment of inflammation and pain as disclosed in Youssefyeh is not the same as treating healed wounds so as to reduce scarring and/or improve the appearance of scars. The methods of the instant invention and those of Youssefyeh are directed to treating completely different conditions. Scarring is not a form of inflammatory dermatoses and likewise, inflammatory dermatoses is not a form of scarring."

Appellant's arguments have been fully considered, but were not found persuasive. As noted by Appellant, Youssefyeh teaches a method for the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, urticaria, psoriasis, erythema), gingivitis and acute injury. Appellant's argument that "Youssefyeh does not teach or suggest a method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars" was not persuasive since the secondary reference of Lee clearly resolves the deficiency of the

Youssefyeh primary reference in their teaching of a method for improving the size and appearance of scar tissue associated with keloids or hypertrophic wound healing disorders. See Abstract of Lee. Applicant argues that the "treatment of inflammation taught by Youseffyeh is a different condition than that of treating a healed wound so as to reduce scarring." This argument was not deemed convincing, as inflammation can occur as a result of a wound, and thus, there is a direct correlation between the two. Applicant also argues that "Scarring is not a form of inflammatory dermatoses and vice versa." This was not persuasive because scarring, such as keloid formation, can occur as a result of inflammation, either mild or intense. Thus, it cannot be seen as to how the primary reference which teaches a method for the treatment of inflammation would be so far from the method of the instant invention, which aims to treat healed wounds (i.e., keloids), particularly since inflammation can result in scar formation of keloids or hypertrophic scarring, for example. In any event, the Lee secondary reference vividly demonstrates the correlation between inflammation and scarring and demonstrates that it is well-known to simultaneously treat inflammatory conditions as well as scars, such as keloids, using their methods of scar treatment. Lee further explicitly teach the use of vitamin E and teach that cells that synthesize collagenase are influenced to a great extent by the environment in which they live. Lee teach that this includes cells of connective tissue and migratory cells that accumulate as a result of injury, *inflammation* or immune phenomena. See column 3, lines 58-67. Hence, it would be *prima facie* obvious to one of ordinary skill in the art to employ the teachings of the secondary reference within the teachings of the primary reference because it would permit simultaneous treatment of two diseases or conditions (i.e., inflammation & scarring-keloids).

Appellant argues, "Although Lee is directed to a method for improving the size and appearance of scar tissue, Lee does not teach or suggest the use of a fluid, film-forming carrier to treat a healed wound to reduce scarring or improve the appearance of scars. Moreover, one of skill in the art would not look to the composition disclosed in Youssefyeh to treat scar tissue. There is simply no reason to combine elements of the composition disclosed in Youssefyeh with elements of the composition disclosed in Lee."

The Examiner did not find this argument persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, ample motivation exists to combine the reference of Youssefyeh with Lee. Lee demonstrates and teaches a method of for improving the size and appearance of scar tissue whereby a thermal material, particularly a hydrogel, is applied to cover and maintain contact with the scar. Lee states that their methods are especially beneficial for improving hypertrophic scar formation. Lee further teaches that the normal wound healing process is comprised of three stages, the first of which is the inflammatory phase. Lee establishes that the inflammatory phase is a degradative phase that occurs immediately after injury and provides a means to remove the damaged tissues and foreign matter from the wound. See column 2, lines 41-61. Hence, the secondary reference vividly suggests the direct correlation between inflammation and wounds and wound healing. The

argument that "Lee does not teach a fluid, film-forming carrier" was further not persuasive, since Youssefyeh initially teaches the use of film-forming materials, including cellulosic derivatives, such as methylcellulose and other synthetic polymers. See col. 15, line 61 – col. 17, line 19 of Youssefyeh. Thus, the prior art in combination teaches the same method of treatment using the same process steps and elements as employed by Appellant. One of ordinary skill in the art would have ample motivation to look to the teachings of Lee in order to improve wound healing and the appearance of scars based on Lee's teaching that that his methods are especially beneficial for improving skin wounds, such as keloid and hypertrophic scar formation, which may occur as a result of inflammation.

In response to applicant's argument that "The use of a film-forming carrier to treat a healed wound to reduce scarring or improve the appearance of scars was not known", the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Claim 30:

Appellant argues, "Youssefyeh does not teach or suggest the use of a composition comprising collagenase to treat and/or improve scarring. There is no mention of collagenase in Youssefyeh. Lee is directed to a method for improving scarring comprising stimulating collagenase activity in the scar by applying a thermal insulating material that elevates the surface temperature of the scar. However, there is no mention or suggestion whatsoever in Lee of

including collagenase in a composition for treating and/or reducing scarring, as presently claimed."

The Examiner did not find this argument convincing. As delineated in the Office Action above, while Youssefyeh does not disclose the use of collagenase, the Lee reference was supplied for the teaching of collagenase, which is useful for the effective breakdown and degradation of collagen. Lee amply demonstrates that it is well known to one of ordinary skill in the art to provide for collagenase in order to improve scarring and for the treatment of wound healing for skin disorders. See for instance, column 7, line 44 – col. 8, line 5. Lee further states that the cells that synthesize collagenase are influenced to a great extent by the environment in which they live. This includes the migratory cells that accumulate as a result of injury, inflammation or immune phenomena, as well as the products secreted by these cells (col. 3, lines 58-66). Hence, one of ordinary skill in the art reading the teachings of Lee would evidently conclude that the inclusion of collagenase is beneficial, in that it allows for the necessary degradative processes of collagen, which is essential for ensuring improvement or reduction in scarring. Thus, Appellant's argument that "there is no mention of collagenase in Lee" was not persuasive, since Lee explicitly suggests and teaches stimulation of collagenase activity and teaches that collagenase is a known collagenolytic enzyme involved in the breakdown of collagen and to ultimately yield an improvement in size or appearance of scar tissue.

* * * * *

- **B. Claims 1-16 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Lee (U.S. Pat. No. 5,552,162).**

**Mantelle ('070)** teaches flexible, finite, bioadhesive compositions and methods for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s), a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents (see Abstract); (col. 1, lines 18-34); (col. 4, line 24 – col. 5, line 62).

The composition when administered topically, for example to an area of the skin, delivers a pharmaceutical agent or a combination of agents to produce a local or systemic effect over a prolonged period of time (col. 5, line 65 – col. 6, line 3).

Suitable active agents disclosed for use in the invention include anti-inflammatory drugs, corticosteroids and the like (col. 23, line 32 – col. 41, line 39); claim 4; Examples 30-32.

Suitable adhesive carriers are disclosed at column 12, lines 55-65 and include cellulose derivatives, silicones.

Mantelle teaches the inclusion of enzymes, such as the proteolytic enzyme – collagenase (col. 38, line 4). Mantelle also teaches vitamins, such as vitamin E (col. 41, lines 35-36).

While the prior art does not explicitly teach treatment of "healed wounds", the prior art nonetheless explicitly teaches compositions that are topically applied on the skin for the effective treatment of pain. The method comprises applying a therapeutically effective amount of a pharmaceutical agent, a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent in the carrier. The compositions are suitable for topical application on the skin.

Mantelle does not teach treating a hypertrophic scar.

**Lee ('162)** teach a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound healing disorder that comprises stimulating collagenase activity in the scar. The method comprises covering the scar with a hydrogel or thermally insulated material that elevates the surface temperature of the scar and that can contain a therapeutically effective amount of medicament (see Abstract); (column 1, lines 41-54); (col. 6, lines 17-49); (col. 11, lines 19-34).

The compositions taught by Lee are particularly effective for improving the size and appearance of hypertrophic scars (see claim 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, particularly hypertrophic scars such as taught by Lee within the methods of Mantelle. One would do so with a reasonable expectation of success because Lee explicitly teaches methods for improving the size and appearance of scars whereby the compositions are especially beneficial for improving hypertrophic scar formation. The expected result would an improved method for treating dermal skin conditions.

**(10) Response to Argument (B):**

Appellant argues, "Mantelle does not teach or suggest a method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars. Lee is directed to a method for improving the size and appearance of scar tissue. However, Lee does not teach or

suggest the use of a fluid, film-forming carrier and hardening the carrier into a tangible membrane juxtaposed to the healed wound."

Appellant's arguments have been considered, but were not deemed persuasive. Mantelle, as noted in the Office Action above, teach flexible, finite, bioadhesive compositions and methods for topical application, which comprise an active agent, pharmaceutically acceptable carrier and a solvent for the active agent in the carrier. Suitable active agents that are disclosed include anti-inflammatory drugs, corticosteroids and the like. See col. 23, line 32 – col. 41, line 39. While Mantelle does not teach treatment of healed wounds to reduce scarring and/or improve the appearance of scars and treatment of a hypertrophic scar, the secondary reference of Lee clearly resolves this deficiency of Mantelle based on their teaching of a method for improving the size and appearance of scar tissue associated with keloids or hypertrophic wound healing disorders. See Abstract of Lee. Lee describes and teaches such a method of treating scars, such as hypertrophic scars, whereby a thermal material, particularly a hydrogel, is applied to cover and maintain contact with the scar. Lee states that their methods are especially beneficial for improving hypertrophic scar formation. Thus, Lee recognizes the same methods as claimed by Appellant for reducing scarring and/or improving the appearance of scars. The argument that "Lee does not teach a fluid, film-forming carrier" was further not persuasive, since Lee was relied upon for the teaching of the treatment of hypertrophic scar tissue, which is clearly suggests and teaches. Moreover, the Examiner notes that Mantelle initially teaches the use of suitable carriers including cellulose derivatives and silicones and thus meets this claim limitation requirement. See column 12, lines 55-65 of Mantelle. Hence, the prior art in combination

teaches the same method of treatment using the same process steps and elements as employed by Appellant.

Appellant argues, "There is simply no reason to combine elements of the composition disclosed in Mantelle with elements of the composition disclosed in Lee, which teaches a composition for treating scar tissue."

This argument was not convincing. Mantelle teaches methods for topical application of flexible bioadhesive compositions that comprise pharmaceutical agent(s) (i.e., anti-inflammatory drugs, corticosteroids), a pharmaceutically acceptable carrier, a solvent for the pharmaceutical agent(s) in the carrier, vitamins (vitamin E) and proteolytic enzymes (collagenase). The reference recognizes and teaches that the compositions are effective for topical application on the skin. While treatment of "healed wounds to reduce and/or improve scarring" is not discussed, the Examiner notes that Lee nonetheless demonstrates the same methods as claimed by Appellant for reducing scarring and/or improving the appearance of scars using the ingredients claimed herein. Consequently, one of ordinary skill in the art would have ample motivation to look to the teachings of Lee in order to improve wound healing and the appearance of scars based on Lee's teaching that that his methods are especially beneficial for improving skin wounds, such as keloid and hypertrophic scar formation, which may occur as a result of inflammation. Both references are drawn to methods for treatment of skin disorders and conditions based upon topically-applied compositions and processes. Thus, it would be *prima facie* obvious to one of ordinary skill in the art to employ the teachings of the secondary reference within the teachings of the primary reference because it would ultimately permit treatment of various skin conditions and disorders. The reason or motivation to modify the

reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

In view of the teachings of the art supplied above, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, based on the combined disclosure of Youssefyeh and Mantelle, both taken in view of Lee.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618